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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CHRISTIAN KROPF, MARCEL ROTH, ULRIKE BRUENINGHAUS, STEFAN MUELLNER, ALBRECHT WEISS, ULRICH SCHOERKEN, LOTHAR KINTRUP, BURKHARD ESCHEN, AMERIGO PASTURA, PETER WUELKNITZ, RUEDIGER KNIEP, HANS LASKA, MICHAEL MEINDERS, and HANS DOLHAINE

Appeal 2009-0827 Application 10/030,268 Technology Center 1600

Decided: May 1, 2009

Before ERIC GRIMES, LORA M. GREEN, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, Administrative Patent Judge.

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a dental care product. We have jurisdiction under 35 U.S.C. § 6(b). We affirm. *Statement of the Case*

Background

"Phosphate salts of calcium have for a long time been added either as abrasive components or to promote remineralization of tooth enamel to formulations of dental cleaning products" (Spec. 1, Il. 12-15). The Specification notes that "calcium fluoride has also been described a number of times as a constituent of dental cleaning products" (Spec. 1, Il. 19-20).

The Claims

Claims 16, 17, 20, 21, 28, and 31-37 are on appeal. We will focus on claims 16 and 33 which are representative and read as follows:

16. A composite material comprising:

- (a) one or more poorly water-soluble phosphate salts of calcium, fluoride salts of calcium, or fluorophosphate salts of calcium, which salts may also contain hydroxyl and/or carbonate groups, the calcium salt or salts being in the form of crystalline, rodlet-like primary nanoparticles having a mean particle diameter of 10 to 300 nm; and
- (b) protein components selected from the group consisting of collagen, gelatine, keratin, wheat protein, rice protein, soya protein, almond protein, oat protein, pea protein, potato protein, yeast protein and hydrolyzates and hydrolyzate derivatives thereof wherein the composite is a microscopically heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein component.

33. A composite material comprising:

(a) one or more poorly water-soluble phosphate salts of calcium, fluoride salts of calcium, or

fluorophosphate salts of calcium, which salts may also contain hydroxyl and/or carbonate groups, the calcium salt or salts being in the form of crystalline, rodlet-like primary nanoparticles having a mean particle diameter of 10 to 300 nm; and

(b) a protein component wherein the protein component is gelatin and/or a hydrolyzate thereof and wherein the composite is a microscopically heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein component.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Bristow et al.	U.S. 4,933,173	Jun. 12, 1990
Rudin et al.	WO 99/20237 A1	Apr. 29, 1999

The issue

The Examiner rejected claims 16, 17, 20, 21, 28, and 31-37 under 35 U.S.C. § 103(a) as being obvious over Rudin and Bristow (Ans. 3-4).

The Examiner finds that Rudin teaches a "hydroxyapatite composite comprising finely divided rod like particles of hydroxyapatite having dimensions of 60nm (L) by 15nm (W) by 5nm (T) (see page 2 paragraph 5) and a surfactant (see page 4 paragraph 4 and Example 5 which includes polyethylene glycol) which can be used to prepare toothpastes (see Abstract)" (Ans. 3). The Examiner finds that Rudin does "not teach the incorporation of a protein, protein hydrolyzate or protein hydrolyzate derivative into the composite. Bristow et al. teach an oral preparation for example a toothpaste comprising hydroxyapatite and casein and explain that casein is an anti-caries agent" (Ans. 4).

Appellants contend that the "Examiner has not shown that the combination of the teachings of Rudin and Bristow teach or suggest the claim limitation that the claimed composite is a *microscopically* heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein" (App. Br. 10). Appellants also contend that "[a] person of ordinary skill in the art, upon reading the teachings of Bristow, would be discouraged from combining casein and fluorine-containing materials in making an anti-caries oral composition" (App. Br. 11).

In view of these conflicting positions, we frame the obviousness issue before us as follows:

Did the Examiner err in finding that Rudin and Bristow render it obvious to form the composite material of claims 16 and 33? *Findings of Fact (FF)*

- 1. Rudin teaches a composition which "may be used for preventive treatment and combatting caries, parodenitis and paradentosis" (Rudin, abstract).
- 2. Rudin teaches that "stomatic compositions comprising hydroxyapatite (HA) have found an extensive application in the stomatologic practice . . . a stomatic composition . . . according to Patent EP 0344832 . . . comprises save the stated HA, water-soluble casein material or sodium trimetaphosphate, as an anti-caries agent and also other well known ingredients" (Rudin 1).
- 3. Rudin teaches that the composition comprises "particles of hydroxyapatite with an average particle size in length (l), width (d) and

thickness (h) of about l = 0.06 μ m +/- 50 %, d = 0.015 μ m +/- 50 % and h = 0.005 μ m +/- 50 %" (Rudin 2, 1l. 29-32).

- 4. Rudin teaches that the hydroxyapatite "possesses osteoreparative properties and contains preferably about 100% Ca₁₀(PO₄)₆(OH)₂" (Rudin 3, 1l. 3-5).
- 5. Bristow teaches "oral preparations having an anti-caries activity" (Bristow, col. 1, ll. 5-6).
- 6. Bristow teaches "[i]t is known from EP-A-73 210 . . . to employ certain water-soluble casein materials as anti-caries agents" (Bristow, col. 1, ll. 14-17).
- 7. Bristow teaches that "calcium phosphate complexes of the tryptic digest of casein are disclosed as anti-caries agents" (Bristow, col. 1, ll. 49-51).
- 8. Bristow teaches "a substantially fluorine free anti-caries oral composition comprising finely-divided hydroxyapatite and an anti-caries agent selected from water-soluble casein materials" (Bristow, col. 1, l. 68 to col. 2, l. 3). Bristow teaches toothpastes composed of hydroxyapatite and casein in Examples 1, 2, 4, and 5 (Bristow, col. 3-4).
- 9. The Examiner finds that "[o]ne of ordinary skill in the art would have been motivated to combine" Rudin and Bristow because Bristow teaches "that hydroxyapatite and casein are compatible and further that casein has anti-caries properties, both of which are reasons to add casein to a toothpaste and cause one of ordinary skill in the art to expect a better product" (Ans. 4).

10. The Specification teaches that "[w]ater-soluble polymeric protective colloids are understood as meaning high molecular weight compounds which are adsorbed on the surface of the nanoparticles and modify these such that they are hindered from coagulating and agglomerating. Suitable polymeric protective colloids are . . . gelatin, casein," etc. (Spec. 6, Il. 27-34).

Principles of Law

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

"Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). "Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to

manufacture products or to obtain and compare prior art products." *Id.* at 1255.

Analysis

Appellants' dispute centers on whether the combination of Rudin and Bristow satisfies the limitation in claim that the "composite is a microscopically heterogenous aggregate of the nanoparticles associated onto the skeleton of the protein" (Claim 16). However, this situation is similar to that in *Kubin*, where the court found that "[e]ven if no prior art of record explicitly discusses the 'wherein the polypeptide binds CD48' aspect of claim 73, the Kubin-Goodwin application itself instructs that CD48 binding is not an additional requirement imposed by the claims on the NAIL protein, but rather a property necessarily present in NAIL." *In re Kubin*, ___ F.3d _____, ____, 2009 WL 877646, *6 (Fed. Cir. April 3, 2009).

Similarly, Appellants' Specification teaches that "high molecular weight compounds . . . are adsorbed on the surface of the nanoparticles and modify these such that they are hindered from coagulating and agglomerating. Suitable polymeric protective colloids are . . . casein" (Spec. 6, Il. 27-34). Thus, it is reasonable to conclude that substituting the hydroxyapatite nanoparticles of Rudin for the hydroxyapatite particles of Bristow in Bristow's hydroxyapatite and casein composition would inherently result in a microscopically heterogenous aggregate of the nanoparticles associated onto the skeleton of the protein as required by claim 16. *See In re Wiseman*, 596 F.2d 1019, 1023 (CCPA 1979) (rejecting the notion that "a structure suggested by the prior art, and, hence, potentially in the possession of the public, is patentable . . . because it also possesses an

Inherent, but hitherto unknown, function which [patentees] claim to have discovered. This is not the law. A patent on such a structure would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art.").

Appellants have provided no proof that a microscopically heterogenous aggregate of the nanoparticles associated onto the skeleton of the protein would not inherently result from the use of Rudin's nanoparticles in the casein and hydroxyapatite composition of Bristow. *See In re Best*, 562 F.2d at 1255 ("Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.").

We are not persuaded by Appellants' argument that "[a] person of ordinary skill in the art, upon reading the teachings of Bristow, would be discouraged from combining casein and fluorine-containing materials in making an anti-caries oral composition" (App. Br. 11). Both Bristow and Rudin teach compositions which combine hydroxyapatite with casein (FF 2, 6, 8). While Appellants are correct that Bristow does not wish to add fluorine materials to the composition, Bristow directly and clearly motivates the addition of casein to anti-caries compositions, noting "[i]t is known from EP-A-73 210 . . . to employ certain water-soluble casein materials as anti-caries agents" (Bristow, col. 1, ll. 14-17; FF 6). Since Rudin does not teach an addition of fluorine materials either (see Rudin 6, example 1), there is nothing in either reference which teaches away from the combination of

casein and hydroxyapatite. Like our appellate reviewing court, "[w]e will not read into a reference a teaching away from a process where no such language exists." *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006).

We are also not convinced by Appellants' argument that the "Examiner has not considered the instantly claimed subject matter as a whole" (App. Br. 11). In *O'Farrell*, the Court found an invention obvious where there was "detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful." *In re O'Farrell*, 853 F.2d 894, 902 (Fed. Cir. 1988). Rudin teaches hydroxyapatite nanoparticles for caries treatment along with other components (FF 1-4), Bristow provides a specific methodology and suggestion for combining hydroxyapatite and casein (FF 5-8), and Bristow shows a successful toothpaste composition with casein and hydroxyapatite (FF 8). The Specification teaches that the combination of casein and nanoparticles of hydroxyapatite will inherently adsorb (FF 10). We find that considered as a whole, the combination of Rudin and Bristow render the claimed invention obvious.

Conclusions of Law

The Examiner did not err in finding that Rudin and Bristow render it obvious to form the composite material of claims 16 and 33.

SUMMARY

In summary, we affirm the rejection of claims 16 and 33 under 35 U.S.C. § 103(a) as obvious over Rudin and Bristow. Pursuant to 37 C.F.R. §

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41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 17, 20, 21, 28,

31, 32, and 34-37 as these claims were not argued separately.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

<u>cdc</u>

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